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DEPARTMENT OF HEALTH AND HUMAN SERVICES M908N

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
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# WARNING LETTER

FLA-97-57

May 12, 1997

Steven M. Bogen
Chief Executive Officer
The Fresh Juice Company
35 Walnut Avenue, Suite 4
Clark, New Jersey 07066

Dear Mr. Bogen:

During an inspection of your firm, located at 1000 American Superior Boulevard, Winter Haven, Florida, conducted on December 2-4, 1996, by FDA Investigator Nicolas Rivera, examples of your product labels for blended juice products identified as "JUST PIK'T FORTIFIED BERRY CHROMIUM," "JUST PIK'T FORTIFIED ORANGE ANTI OXIDANT," and "JUST PIK'T FORTIFIED PINA COLADA," were obtained for review and evaluation.

We have determined that your labels are in serious violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and the Food Labeling Regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), as explained below:

## JUST PIK'T FORTIFIED BERRY CHROMIUM

The product is misbranded within the meaning of Section 403(i)(2) of the Act in that the product purports to be a beverage containing grape and apple juice from concentrate, and the label fails to bear a statement of the total percentages of each fruit juice contained in the product [21 CFR 101.30(b)(1)].

The product is also misbranded within the meaning of Section 403(r)(2)(B) of the Act in that the label bears the nutrient content claim "FORTIFIED" but fails to bear the required referral statement "See ___ for nutrition information" [21 CFR 101.13(g)].

The product is further misbranded within the meaning of Section 403(q)(1) of the Act in that the label fails to bear the nutrition information in the format required [21 CFR 101.9]. The serving size declaration "8 fl. oz. (240 ml)" should be declared as "Serving Size 1 bottle (11.5 fl. oz.)" since this is a single serving container and the

declaration "Servings Per Container" is not required. The nutrient levels declared are only about two-thirds the amount they should be and misrepresent the nutrient profile for this product because the labeled serving size is only about two-thirds of the required amount. The nutrition information must be revised to reflect this change in serving size.

JUST PIK'T FORTIFIED ORANGE ANTI-OXIDANT

The product is misbranded within the meaning of Section 403(r)(1)(B) of the Act in that the label bears the health claim "Beta Carotene, Anti-Oxidant, believed to promote a healthy heart & assist in Cancer prevention," a claim specifically not authorized by FDA [21 CFR 101.71(c)].

The product is misbranded within the meaning of Section 403(i)(2) of the Act in that the product purports to be a beverage containing fresh orange juice, apple and grape juice from concentrate, and the label fails to bear a statement of the total percentages of each fruit juice contained in the product [21 CFR 101.30(b)(1)].

The product is also misbranded within the meaning of Section 403(r)(2)(B) of the Act in that the label bears the nutrient content claim "FORTIFIED" but fails to bear the required referral statement "See ___ for nutrition information" [21 CFR 101.13(g)].

The product is further misbranded within the meaning of Section 403(q)(1) of the Act in that the label fails to bear the nutrition information in the format required [21 CFR 101.9]. The serving size declaration "8 fl. oz. (240 ml)" should be declared as "Serving Size 1 bottle (11.5 fl. oz.)" since this is a single serving container and the declaration "Servings Per Container" is not required. The nutrient levels declared are only about two-thirds the amount they should be and misrepresent the nutrient profile for this product because the labeled serving size is only about two-thirds of the required amount. The nutrition information must be revised to reflect this change in serving size.

JUST PIK'T FORTIFIED PINA COLADA

The product is misbranded within the meaning of Section 403(r)(1)(A) of the Act in that:

a) The label bears the nutrient content claim "PROTEIN-HIGH" for which the product fails to qualify in that it contains less than 20% of the daily recommended value (DRV) established for protein per serving [21 CFR 101.54(b)].

b) The label bears the implied nutrient content claim "energy boost" which implies that the product is high in calories, a claim not authorized by FDA at this time.

The product is misbranded within the meaning of Section 403(i)(2) of the Act in that the product purports to be a beverage containing pineapple juice from concentrate, and the label fails to bear a statement of the total percentage of fruit juice contained in the product [21 CFR 101.30(b)(1)].

The product is also misbranded within the meaning of Section 403(r)(2)(B) of the Act in that the label bears the nutrient content claim "FORTIFIED" but fails to bear the required referral statement "See ___ for nutrition information" [21 CFR 101.13(g)].

The product is further misbranded within the meaning of Section 403(q)(1) of the Act in that the label fails to bear the nutrition information in the format required [21 CFR 101.9]. The serving size declaration "8 fl. oz. (240 ml)" should be declared as "Serving Size 1 bottle (11.5 fl. Oz.)" since this is a single serving container and the declaration "Servings Per Container" is not required. The nutrient levels declared are only about two-thirds the amount they should be and misrepresent the nutrient profile for this product because the labeled serving size is only about two-thirds of the required amount. The nutrition information must be revised to reflect this change in serving size.

These violations concern certain new labeling requirements. Final regulations promulgated under the Nutrition Labeling and Education Act of 1990, as published in the Federal Register, went into effect on May 8, 1994, except for those firms which applied for and received an extension until August 8, 1994, or an exemption. Although you may have qualified for an exemption based upon your firm's size and/or the amounts of products produced, the inclusion of nutrition information on your labels disqualifies you from any exemptions. These regulations require additional changes in your labels, including changes and additions to the nutrition labeling of your products.

The above violations are not intended to be an all-inclusive list of deficiencies regarding products labeled by your firm. The comments above pertain only to those products selected for review. Other label violations can also subject your food products to legal action. As the chief executive officer, it is your responsibility to assure that appropriate changes are made to your labels to bring all of your products into compliance with the Act. You should take prompt action to correct these violations. Failure to take such action may result in regulatory action, such as seizure or injunction, without further notice.

In addition, all of the above product labels bear the nutrient content claim "no sugar added" but fail to bear a statement that the food is not "low calorie" or "calorie reduced" as required [21 CFR 101.60(c)(2)(v)].

We also point out that the American Technology Preeminence Act of 1991, which became effective on February 14, 1994, requires that label declarations of net quantity of contents bear a statement of quantity in terms of the metric weight system as well as the customary avoirdupois (pound and ounce) system. However, FDA has not published final regulations on how the declaration is to be made. The agency recommends that if a firm wishes to avoid having to change labels again when the regulations on the metric declaration become effective, the firm should add the metric contents statements now, using the guidance provided in the proposed regulations published in the Federal Register of December 21, 1993. We expect that any differences between that proposal and the final regulations will be minor and will not by themselves require a label change.

We request that you notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you have taken to correct these violations, and to assure that similar violations will not recur. Your response should include a copy of your proposed new labels, and a proposed time frame for their implementation.

Your reply should be directed to the Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen
Director, Florida District

cc: Bryan Duffy, President
The Fresh Juice Company
of Florida, Incorporated
1000 American Superior Blvd.
Winter Haven, Florida 33606